REMARKS

Applicant notes with appreciation the well-reasoned comments embodied in Paper No. 20080713. This amendment is submitted to be fully responsive thereto with the specifics of the above claim amendments being detailed in the context of a particular outstanding rejection.

Currently, claims 1, 3-12, 15-19, 21-28 and 39 stand rejected under 35 U.S.C. §112, first paragraph, as to enablement. Additionally, these claims are also currently rejected under 35 U.S.C. §112, second paragraph.

Remarks Directed to Claim Rejections under 35 U.S.C. §112, First Paragraph

By way of this amendment, claims 1 and 15, the only independent claims, have been amended within their preamble to recite a "process for detecting an elongated oligonucleotide". This amendment and commensurate amendments made within the bodies of each of these independent claims are submitted to fully address the assumed claim construction for the purpose of examination articulated in Paper No. 20080713, section 4, page 2.

With respect to claim 1, the claimed invention overcomes several of the time-consuming steps associated with prior art detection methodologies and specifically teaches the ability to detect an elongated oligonucleotide without the need for separation methods such as fluorescence polarization (page 7, lines 7-27) where the fluorescence polarization signal is indicative of size of the oligonucleotide and as such the labeled oligonucleotide signal changes after the oligonucleotide has been lengthened to form an elongated oligonucleotide. Based on the highly detailed example provided in the specification as filed as Example 2, Applicant respectfully submits that one of skill in the art would be able to detect the elongated oligonucleotide as per claim 1 based on a greater than 15% increase in fluorescence polarization (301 mP versus 258 mP for reference).

Based on the amendments to claim 1 to recite detection of an elongated oligonucleotide as opposed to a kinetic related event of oligonucleotide elongation, reconsideration and withdrawal of the rejection as to claim 1 and those claims that depend therefrom under 35 U.S.C. §112, first paragraph, is requested.

With respect to independent claim 15, in which a fluorescence parameter is measured to obtain a test measurement of the elongated oligonucleotide, the test measurement is compared with a reference measurement. The basis of the rejection is that claim 15 fails to recite the timing of the reference measurement relative to the test measurement as well as being silent as to whether an elongated oligonucleotide has been formed.

Claim 15 has been amended to recite that the test of the reference measurement differs "in the elongated oligonucleotide present relative to the test measurement". Support for this limitation is found in the instant specification at page 10, line 29 – page 11, line 3. Applicant respectfully submits that this amendment is sufficient to confer on one of ordinary skill in the art sufficient information to make and use the invention as claimed. It is submitted that one of ordinary skill in the art appreciates that a reference measurement need only vary in the elongated oligonucleotide concentration to provide the relative baseline to the test measurement. As such, a reference measurement is appreciated by one of ordinary skill in the art to be meaningful comparative value when taken at different times or from a duplicate oligonucleotide elongation reaction mixture, as articulated in original claims 16-19. These aspects of how to use a reference in fluorescence measurements and detection of nucleic acids has been described in U.S. Patent 6,022,686 as originally indicated in the specification at page 11, lines 3-4 for this specific purpose.

In light of the above amendments and remarks, independent claim 15 and those claims that depend therefrom are submitted to be properly enabled and as such reconsideration and withdrawal of the rejection as to these claims under 35 U.S.C. §112, first paragraph, is requested.

With respect to claim 39, the above remarks provided with respect to the reference measurement are considered to be equally applicable hereto with the exception that unlike the subject matter of independent claim 15 which entailed detection of an elongated oligonucleotide, claim 39 pertains to detection of an oligonucleotide hybrid.

Additionally, in Paper No. 20080713, section 11 (pages 4-5), it is noted the concern that the methodology of claim 39 potentially encompasses a circumstance in which no meaningful result is obtained. With respect to this concern, Applicant submits that the holdings of *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) as to a "reasonable correlation" standard indicate that this is not a basis for an enablement rejection as there are embodiments of claim 39 which are operative. These embodiments are readily apparent to one of ordinary skill in the art, especially in light of this person not being a mindless automaton in keeping with the holdings of *KSR*. Additionally, the amendments to claim 39 that provide detection of the oligonucleotide hybrid, one of ordinary skill in the art would appreciate that duplication of the process according to claim 39 as a function of stringency conditions would provide data not only to the production of the oligonucleotide hybrid but also provide information as to the robustness of the resulting hybrid. Additionally, one of skill in the art is submitted to have the knowledge that performing a reference measurement on a hybridization reaction mixture devoid of polypeptide or potentially hybridizing other nucleic acid sequences could readily discount or compensate for the possibility of self-hybridization or dimerization, concerns articulated in

section 11 of the outstanding Office Action. Reference measurement procedures known to the art are embodied in the instant specification at page 8, line 6 – page 9, line 25.

In light of the above amendments and remarks, reconsideration and withdrawal of the rejection as to claim 39 under 35 U.S.C. §112, first paragraph, is requested.

Remarks Directed to Pending Claims under 35 U.S.C. §112, Second Paragraph

The basis of this rejection as to all the pending claims is that an essential step has been omitted from the claims, specifically "steps which will result in a meaningful result be[ing] obtained from each of the methods of detecting oligonucleotide elongation as well as a method of detecting a hybrid oligonucleotide." (Paper No. 20080713, section 16, page 5).

With respect to independent claims 1 and 15, reconsideration of this rejection is respectfully requested on the basis that these claims in current form recite detection not of oligonucleotide elongation but rather detection of an "elongated oligonucleotide". Based on the fact that these claims no longer include a kinetic aspect in that detection follows as a function of time the mechanistic formation of an elongated oligonucleotide, it is respectfully submitted that the rejection as to claims 1, 3-12, 15-19 and 21-28 under 35 U.S.C. §112, second paragraph, is no longer proper and it is respectfully requested that it be withdrawn.

With respect to claim 39, claim 39 now recites comparison of a test measurement with a reference measurement "to detect the oligonucleotide hybrid" with the test measurement being taken "under hybridization conditions". Support for the amendment that the hybridization reaction mixture is subjected to hybridization conditions so as to form an oligonucleotide hybrid and thereby allow detection of the same is submitted to be found throughout the specification as filed as well as the claims as filed and includes Example 2 (page 10, line 15 and beyond) and

page 8, line 24 – page 9, line 2. With this amendment to claim 39, any rejection associated therewith as a result of an omitted step is believed to have been overcome.

Claim 39 is also considered to be indefinite as to the metes and bounds of the term "oligonucleotide hybrid". In this regard, the Examiner's attention is drawn to page 4, lines 10-12. It is submitted that one of ordinary skill in the art would appreciate that a nucleic acid complex formed through hybridization reaction is fairly termed an oligonucleotide hybrid. To make this explicit, claim 39 has been amended to recite an oligonucleotide hybrid of a DNA:DNA, DNA:RNA, or RNA:RNA complex. With this amendment, claim 39 is respectfully submitted to satisfy the requirements of 35 U.S.C. §112, second paragraph.

Reconsideration and withdrawal as to the rejection of all the pending claims under 35 U.S.C. §112, second paragraph, is therefore requested.

Summary

Claims 1, 3-12, 15-19, 21-28 and 39 remain pending in the application. Entry of this amendment and the passing of this application to allowance are requested. Should the Examiner have any suggestions as to how to improve the form of any of the pending claims, it is respectfully requested that the undersigned attorney in charge of this application be contacted at the telephone number given below.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180.

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Respectfully submitted,

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